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November 19, 2004

Office of Nutritional Products,
Labeling and Dietary Supplements (HFS-810),
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Brush Pkwy.
College Park, MD 20740

NOV 23 2004

Section 403(r) (6) Notification

Dear Sir or Madam:

In accordance with the requirement of section 403(r) (6) of the Federal Food, Drug and Cosmetic Act, **Leiner Health Products** notifies the FDA that it has begun using the following phrase and statement:

**Helps Reduce Hot Flashes & Night Sweats
Natural Approach for Menopausal Symptoms**

Emotional and physical changes can appear long before the onset of menopause. *estro Vital Nutrients*TM supplies a natural approach to help relieve menopausal symptoms.

Calcium develops healthy bones.

Magnolia Bark Extract and Date Seed Extract enhance a good night's sleep and can help to even out the mood swings.

Natural sources of vitamin E, folic acid and B-6 to promote heart health.

on the following product:

***estro Vital Nutrients*TM**

Very truly yours,

Leiner Health Products

A handwritten signature in cursive script, reading 'Kristi Ansnes', written over a horizontal line.

Kristi Ansnes
Regulatory Affairs Associate

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Office of Nutritional Products,
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Food and Drug Administration
(Continued)

The following brands also use the above statement:

Albertson's
BI-MART
BIO BALANCE®
COUNCIL LABS®
CVS®
ECKERD®
equate®
Hannaford®
HealthLine
health PRIDE
Kash n' Karry
KIRKLAND Signature™
Kroger®
Longs
MARC'S
Member's Mark
MEIJER™

Nature's Origin®
NATURE'S VALLEY™
NATURITE®
NUTRA CHOICE
NUTRI-BLEND
Oscor®
PHARMACIST FORMULA®
BODYCOLOGY™
SAFEWAY SELECT™
Sav•on™
Shaw's
ShopKo®
Spring Valley®
TARGET®
TOP CARE®
TRUNATURE®
Wegmans®